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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,477	09/18/2003	David L. Evans	HO-P02228US1	8875
26271	7590	04/05/2006	EXAMINER	
FULBRIGHT & JAWORSKI, LLP 1301 MCKINNEY SUITE 5100 HOUSTON, TX 77010-3095			REIMERS, ANNETTE R	
			ART UNIT	PAPER NUMBER
			3733	

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/666,477

Applicant(s)

EVANS ET AL.

Examiner

Annette R. Reimers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 14, 2006 has been entered.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993)\*, *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985)\*, *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982), *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970)\*, and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7 and 9-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 9-14, 17, 20-22, 25-30 and 33-34 of US Patent Number 6,652,586. Although the conflicting claims are not identical, they are not patentably distinct from each other, because the

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difference between claim 7 and 9-13 of the application and claims 1-6, 9-14, 17, 20-22, 25-30 and 33-34 of the patent lies in the fact that the patent claim includes many more elements and is thus much more specific. Thus, the invention of claims 1-6, 9-14, 17, 20-22, 25-30 and 33-34 is in effect a "species" of the "generic" invention of claims 7 and 9-13. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 20 USPQ2d 2010 (Fed. Circ. 1993). Since claims 7 and 9-13 of the application are anticipated by claims 1-6, 9-14, 17, 20-22, 25-30 and 33-34 of the patent, claims 7 and 9-13 are not patentably distinct from claims 1-6, 9-14, 17, 20-22, 25-30 and 33-34.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 11, line 3, "the prosthesis body" lacks proper antecedent basis.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-15 are rejected under 35 U.S.C. 103(a) as being anticipated by Pope et al. (U.S. Patent Number 6,290,726) in view of Raab (U.S. Patent Number 4,281,420) and Armini et al. (U.S. Patent No. 5,674,293)

Pope et al. teaches a vertebral disc prosthesis comprising two prosthesis plates, 2051 and 2052, and a prosthesis core, 2053, wherein the prosthesis core articulates against at least one prosthesis plate of the two prosthesis plates permitting a rotational movement around a vertical axis (see figure 2Z). Pope et al. further teaches an irregular textured beaded or mesh surface structure, 234/242, that is adapted to accommodate tissue in-growth on a portion of the prosthesis (see alternative embodiment of Figures 2G and 2J and column 12, lines 25-34, and column 13, lines 23-30). In addition, the irregular surface structure comprises anchoring projections, 220a and 220b (see alternative embodiment of Figure 2I).

Pope et al. discloses the claimed invention except at least one surface of cross-linked polyethylene and at least one component formed of zirconium or zirconium alloy having at least one surface of diffusion-bonded blue-black or black oxidized zirconium. Raab discloses a prosthesis for implantation in a patient comprising at least one surface of cross-linked polyethylene (see figures 1 and 2, column 6, lines 34-68 and column 7, lines 1-3). Furthermore, Raab teaches the use of cross-linked polyethylene in order to increase the mechanical strength of the surface region, wherein a weak boundary layer is transformed into a strong boundary layer (see column 6, lines 60-63). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the prosthetic device of Pope et al. with at least one surface of cross-linked

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polyethylene, in view of Raab, in order to increase the mechanical strength of the surface region, such that a weak boundary layer is transformed into a strong boundary layer.

Armini et al. discloses a prosthesis for implantation in a patient comprising at least one component formed of zirconium or zirconium alloy having at least one surface of blue-black or black oxidized zirconium (see figure 1, abstract, column 6, lines 14-36 column 7, lines 56-67 and column 8, lines 1-9). Armini et al. teaches the use of zirconium or a zirconium alloy having at least one surface of blue-black or black oxidized zirconium in order to provide a low friction, low wear articulating surface and to improve adhesion in order to decrease coating delamination or failure (see abstract and column 2, lines 11-14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the prosthetic device of Pope et al. with at least one component formed of zirconium or zirconium alloy having at least one surface of blue-black or black oxidized zirconium, in view of Armini et al., in order to provide a low friction, low wear articulating surface and to improve adhesion in order to decrease coating delamination or failure. Regarding the diffusion-bonding process, it is noted that black oxidized zirconium utilized by Armini et al. appears to be substantially identical to the black oxidized zirconium claimed, although produced by a different process, therefore the burden is upon the applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983).

Regarding claims 9-10, Pope et al. discloses the claimed invention except for the surface of blue-black or black oxidized zirconium being from about 1 to 20 microns thick or from about 1 to 5 microns thick. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Pope et al. with the surface of blue-black or black oxidized zirconium being from about 1 to 20 microns thick or from about 1 to 5 microns thick, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Pope et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

### ***Response to Arguments***

Applicant's arguments filed on March 14, 2006 have been fully considered, but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually

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where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER